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GB05/921



INVESTOR IN PEOPLE

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I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

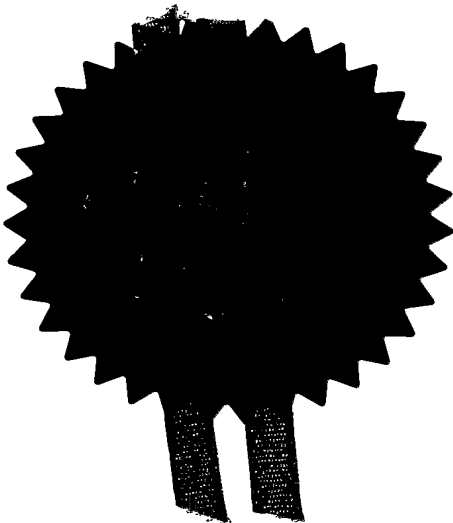
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# Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference	EMS - 1045		
2. Patent application number (The Patent Office will fill in this part)	10 MAR 2004	0405362.5	
3. Full name, address and postcode of the or of each applicant (underline all surnames)	University of Newcastle upon Tyne 6 Kensington Terrace Newcastle upon Tyne NE1 7RU UK		
Patents ADP number (if you know it)			
If the applicant is a corporate body, give the country/state of its incorporation	(GB) 38044009		
4. Title of the invention	Peak Flow Measurement Device		
5. Name of your agent (if you have one)	Technology Transfer Office Research & Innovation Services University of Newcastle 1 Park Terrace Newcastle upon Tyne NE1 7RU		
"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	Morgreaves Elsworth Rotterdam House 116 Quayside Newcastle upon Tyne 6138044008 NE1 30Y 8353526091		
Patents ADP number (if you know it)	N/A		
6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
	N/A		
7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application		Date of filing (day / month / year)
	NA		
8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:	YES		
a) any applicant named in part 3 is not an inventor, or			
b) there is an inventor who is not named as an applicant, or			
c) any named applicant is a corporate body.			
See note (d))			

## Patents Form 1/77

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Continuation sheets of this form	0
Description	5 (X2)
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Priority documents	—
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Statement of inventorship and right to grant of a patent (Patents Form 7/77)	—
Request for preliminary examination and search (Patents Form 9/77)	—
Request for substantive examination (Patents Form 10/77)	—
Any other documents (please specify)	—

11. I/We request the grant of a patent on the basis of this application.

Signature



Date 4<sup>th</sup> March 2004

12. Name and daytime telephone number of person to contact in the United Kingdom P E Harley (Newcastle) 0191 222 5314

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DUPLICATE

## Peak Flow Measurement Device

The invention relates to a device to be used for the measurement of the maximum, or peak, rate of urine flow from human subjects, for clinical analytical purposes. Such a measurement is useful as a standard clinical indicator of urodynamic obstruction. The invention could also be adapted as a low cost tool for the gauging of peak fluid flow in other medical and industrial applications.

A constriction or obstruction of the urethra reduces the flow rate of urine. Prostatic hyperplasia is one example of a condition common in males. Urethra damage resulting from trauma is also common, particularly in the case of road accident victims. In general, a peak urine flow rate in excess of 15 millilitres per second is considered normal for a man. A peak flow rate of less than 10 millilitres per second has a high probability of being associated with an urodynamic obstruction. A measure of peak flow rate therefore provides a useful diagnostic indicator to a physician. Furthermore, the efficacy of treatments for the condition, through surgery, or pharmacological means, may be objectively assessed by measuring urine peak flow rate.

It is desirable to offer a means of peak urine flow measurement that is low cost, does not require the presence of expert staff, and that can preferably be used, unaided, by the patient.

There is a considerable body of prior art in the field. Current use is made of bulky and expensive electronic equipment that measures the peak flow with considerable accuracy, and is often combined with apparatus for retaining the urine sample to allow for laboratory analysis of the urine. Such apparatus requires specially trained staff to operate it, who are required to be present while the urine sample is being provided by the patient. This encroachment on the patient's privacy can interfere with the accuracy of the test result obtained. Other prior art, such as that described in US 4,753,249 represents a variation of a multi-orifice design based on the urinometer of Willard

Drake, and as described in his 1953 patent US 2,648,981. By its use of a simple measurement vessel and orifice, the current invention offers a design of significantly reduced complexity and ease of manufacture, appropriate to the rapid screening of patients suffering urodynamic conditions and without recourse to expert assistance.

The current invention utilises a novel approach to provide a low cost device for the measurement of urine flow in a clinical or home environment. The device may also be adapted for the measurement of liquid flow in other medical or industrial applications where a low cost solution, optionally including that of a disposable one time use device, is appropriate.

The device comprises a vessel formed as a hollow cylinder, solid at one end and open at the other. In use, the cylinder is held vertically, with its solid end downward, and its open end uppermost. A small orifice in the solid end allows liquid within the cylinder to exit at a constricted rate. The open end of the cylinder is available for the introduction of fluid under conditions of non-constricted free flow. The behaviour of fluid progressing through an orifice such as that in the closed end of the cylinder is such that the square of the velocity of the exit stream of fluid is proportional to the height of the fluid in the cylinder. The relationship of the height of the fluid and the orifice radius is determined by the formula, well known in the art of hydrodynamics:

$$\text{Flow Rate} = K\pi r^2 \times \sqrt{(2gh)}$$

Where: K is a constant relating to the configuration of the aperture.

$\pi r^2$  is the area of the aperture.

g is the acceleration due to gravity.

h is the height of fluid in the tube.

Consequently, as fluid is introduced into the cylinder, the height of the fluid will rise initially, and then stabilise at a height at which the efflux through the orifice matches the influx. Provided that the dimensions of the cylinder, and of the orifice, are chosen to be appropriate for the expected total volumetric flow contributing to the measurement, together with the expected flow rates, the maximum height achieved by the fluid in the cylinder will be indicative of the peak influx rate.

The cylinder is preferentially constructed from a transparent material so that either an independent clinician, or the subject him or herself may make note of the height achieved by the fluid during a flow measurement. To assist such measurement, the outer surface of the cylinder may include an engraved or printed scale of a complexity appropriate to the application. In one embodiment of the invention, a simple scale consisting of three coloured bars is used. For the measurement of urine flow in men, a coloured bar would extend from the closed end of the cylinder to the height at which a flow of 10 millilitres per second was appropriate. A differently coloured bar would extend from the height at which a flow of 10 millilitres per second was appropriate to the height at which a flow of 15 millilitres per second was appropriate. A third bar of a third colour would extend beyond this. An optional addition to the scale would be the inclusion of a strip of a suitable heat sensitive material, extending the full length of the cylinder, such that the height gained by a warm fluid in the cylinder could be rendered more apparent to the observer.

The open end of the cylinder may preferentially be connected to a flared receptacle or funnel, to assist the introduction of the fluid into the cylinder.

One embodiment of the invention will now be described by way of example, with reference to the attached diagrams. Figure 1 shows a schematic cross section through the device, which, in this embodiment, is manufactured using vacuum formed plastics, or similar techniques. The cylinder (1) is of 30mm internal diameter, and 200 mm in length. The closed end of the cylinder (2) is perforated by an orifice (3), of 4mm diameter. The upper end of the cylinder is flared to form a catchment funnel (8).

Figure 2 shows an external view of the cylinder. The external surface of the cylinder has affixed a printed label (4), extending the length of the tube, and approximately 10mm wide. The label is coloured red in its lower section (5), yellow in its mid section (6), and green in the upper section (7). The boundary between the red (5) and yellow (6) sections corresponds with a fluid height in the cylinder appropriate to that achieve with a sustained flow of 10ml per second of fluid introduced to the cylinder. The boundary between the yellow (6), and green (7), sections corresponds with a fluid



height in the cylinder appropriate to that achieve with a sustained flow of 15ml per second of fluid introduced to the cylinder.

Figure 3 shows the device in use. In order to measure a patient's peak urine flow, the cylinder is held vertically over a lavatory bowl so that the fluid (9) emerging from the orifice (3) may conveniently be disposed of. Alternatively, a receptacle can be provided if an analysis of the fluid is subsequently required. The patient then directs his urine (10) into the open end of the cylinder through the catchment funnel (8). As the stream of urine enters the cylinder (1), the level of the urine in it rises until the efflux balances the influx of urine, at which point the level (11) remains constant. Ultimately, as the patient's urine flow is exhausted, the level drops, until the device is once again empty. An attendant, or the patient himself, observes the highest level (11) achieved in the cylinder, and notes whether this corresponds with the red (5), yellow (6), or green (7), section of the label (4).

Other colours, and a greater or lesser number of sections may be used where it is considered appropriate. In another similar embodiment, the label's coloured sections are replaced with numbered sections. In a further embodiment for use in paediatrics, smaller dimensions may be adopted for the cylinder and the orifice, and the coloured label is replaced with one which has cartoon characters, or the like, to identify the three sections.

In another embodiment, a strip of liquid crystal or similar heat sensitive indicating film is applied, either independently, or alongside the label. As urine is expelled from the body at an elevated temperature, the cylinder wall will heat up where immersed. By choosing a suitable transition temperature, and a non-reversible type of indicator, a permanent indication of the achieved urine flow may be presented. In a further refinement, the strip is placed on an area of the cylinder whose wall thickness has been reduced in order to maximise the heat transfer.

In yet another embodiment, the internal diameter of the cylinder may be varied along its length in order to provide a greater accuracy of measurement at certain specific measured flow rates of interest.

A further embodiment is shown in Figure 4 which shows the diameter of the cylinder increasing step-wise, at specific measurement heights that relate to significant flow rates. When a subject looks vertically downwards into the cylinder, as might a test subject when urinating into it, concentric rings will thus be observed at the shoulder of each step. As each step shoulder is immersed in urine, the subject may easily assess whether the height achieved by the urine surpasses the step. In the diagram of Figure 4, an orifice (3) of diameter 4.6 mm perforates the solid end of the hollow cylindrical vessel (2), having an internal diameter of 16mm. The orifice is bevelled, such that its diameter increases through the thickness of the solid end of the vessel resulting in a hydro-dynamically thin orifice being presented to the fluid efflux. At a height of 36mm above the orifice (12) the diameter of the vessel expands to 20mm, and at a further height of 46mm, (13) it expands again to 24mm. These heights are chosen such that they correspond to efflux flow rates at the orifice of 10ml per second and 15ml per second respectively. Above the second step the vessel extends further, to a catchment funnel (8). Figure 5a shows the view into the vessel from above, as seen by the subject when the level in the vessel is below the first shoulder step. Figure 5b shows the same view but with urine filling the tube to a level between the two steps, and Figure 5c shows the same view with a level surpassing both shoulder steps. To further enhance the visibility of the step, a series of pyramidal teeth (14) may optionally be incorporated into the rim of the step, which, under lateral illumination, renders even better visibility of their state of immersion in urine, to the observer.



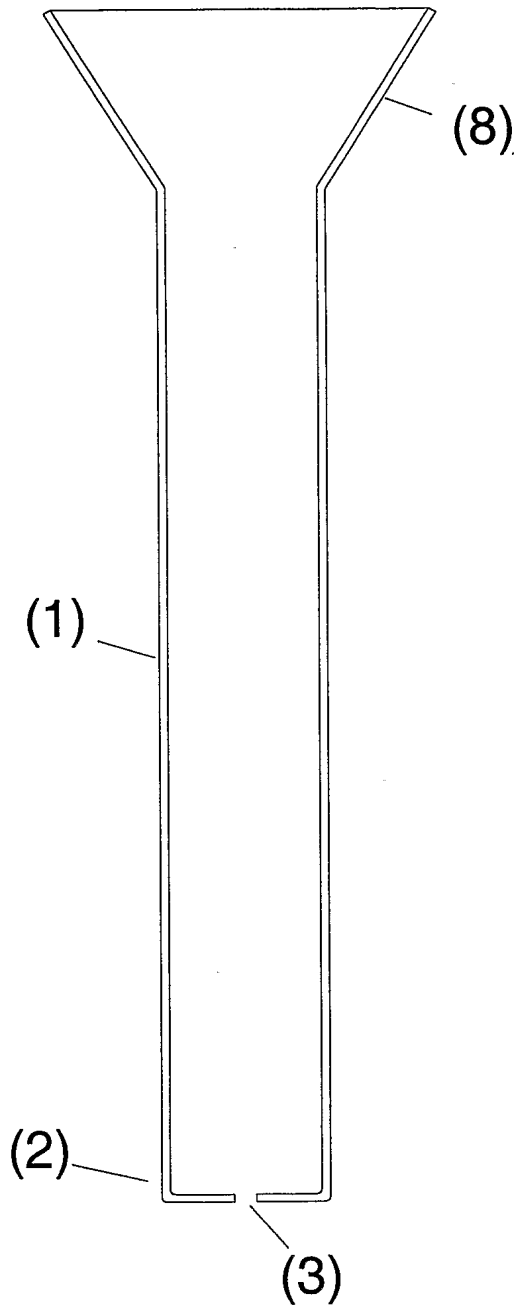


Figure 1

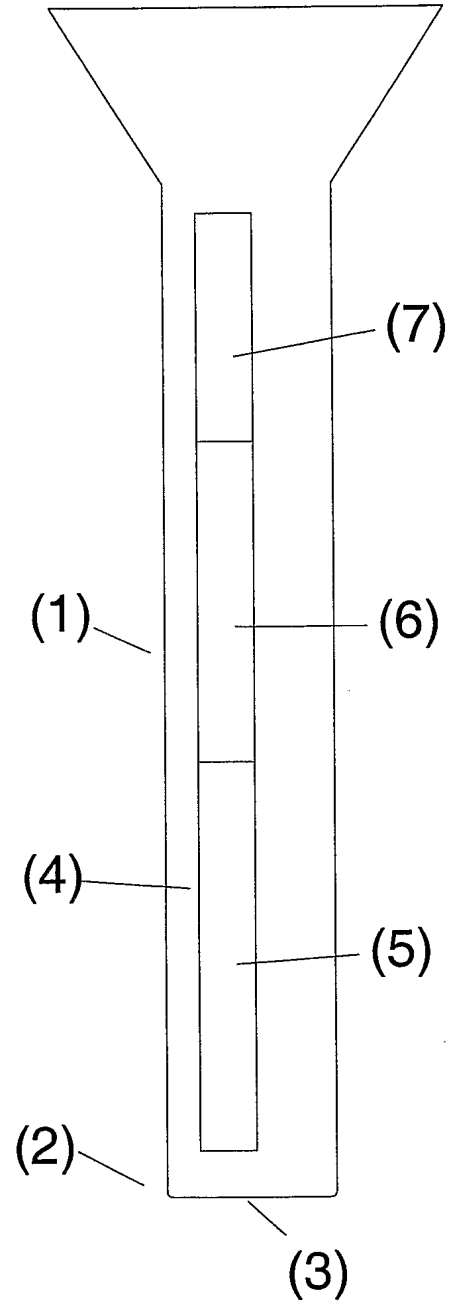


Figure 2



2/3

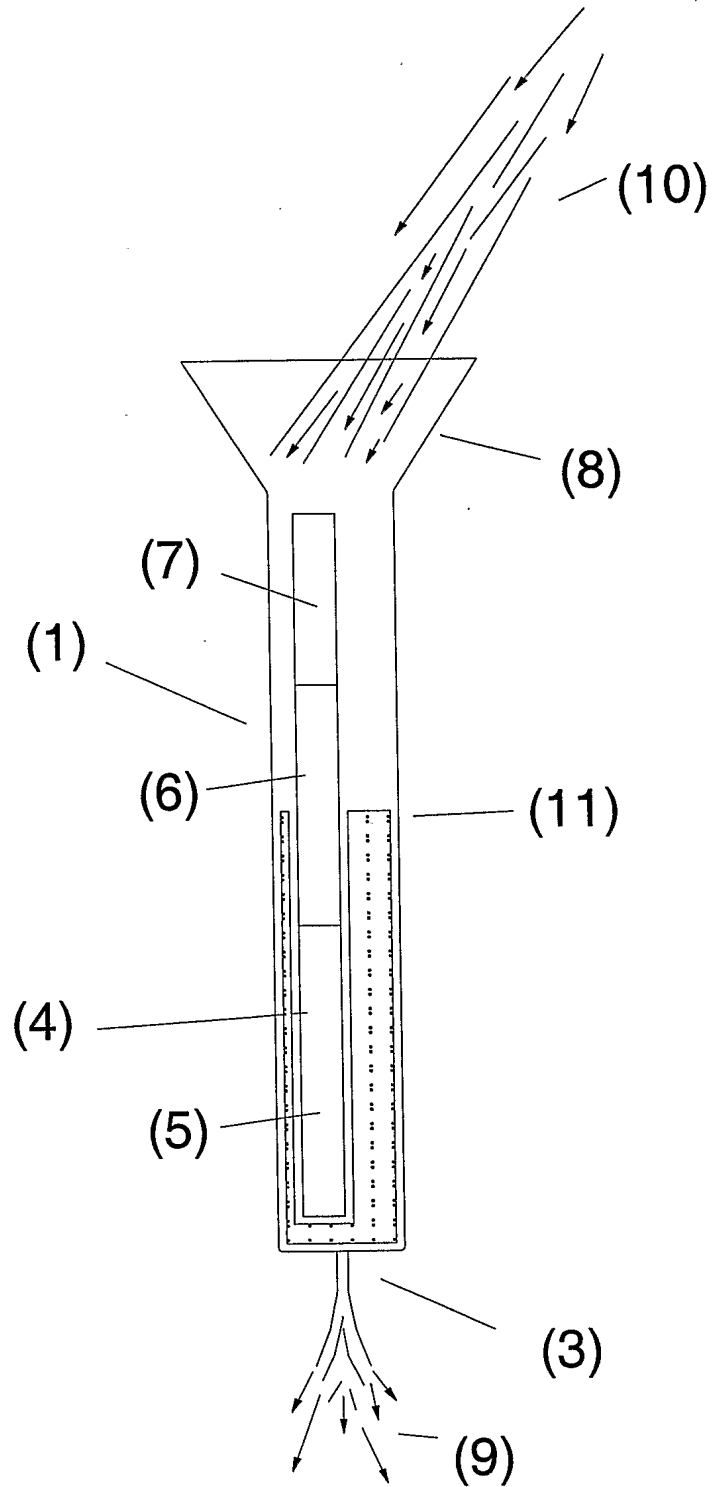


Figure 3



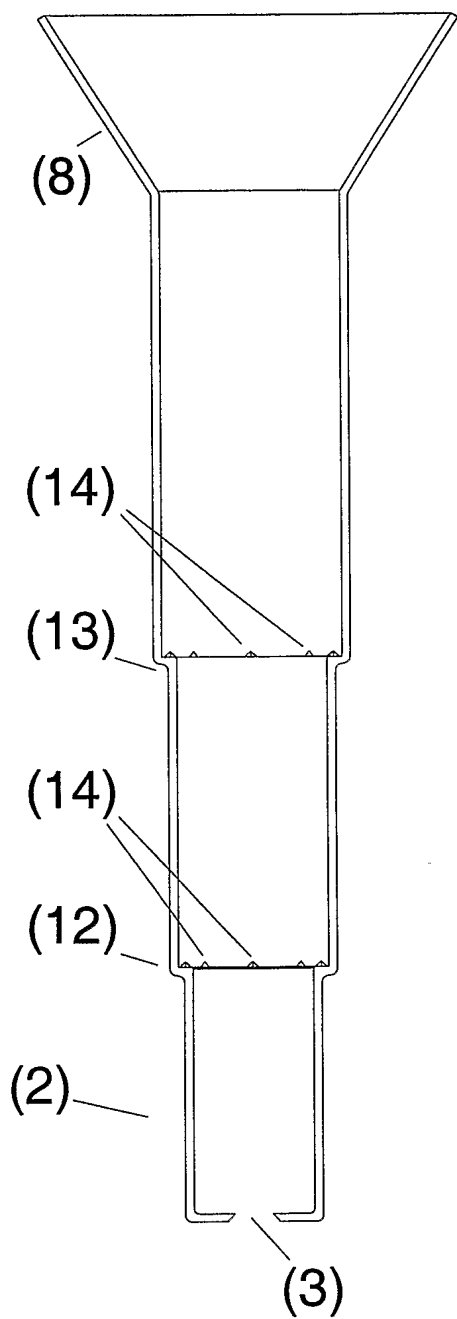


Figure 4

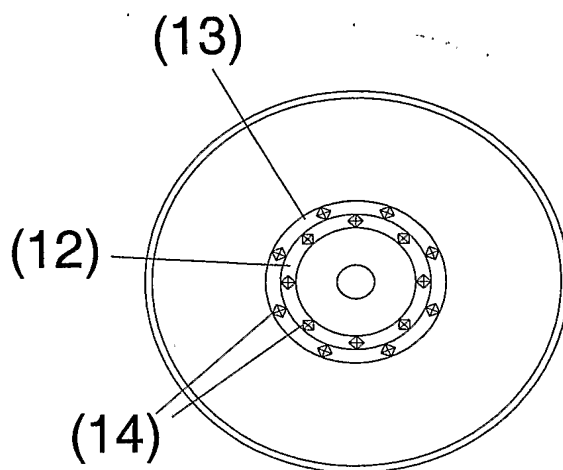


Figure 5 a)

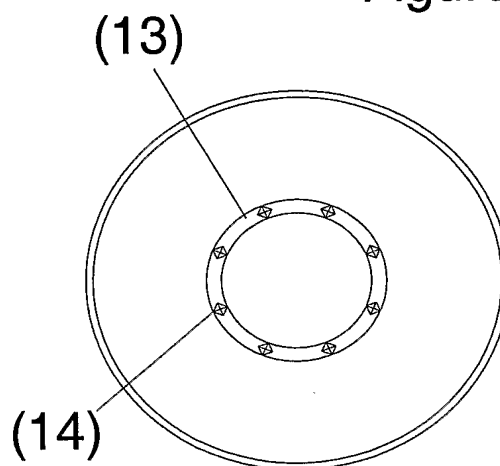


Figure 5 b)

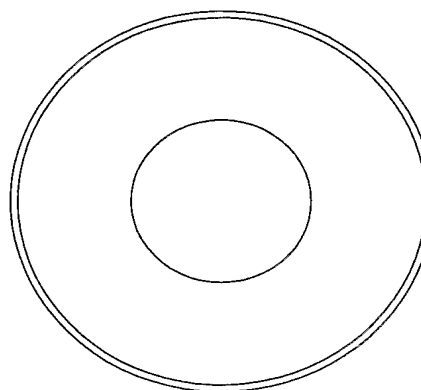


Figure 5 c)



